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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,759	02/21/2006	Yutaka Harano	AI 402NP	6656
23995 7590 06/18/2010 RABIN & Berdo, PC 1101 14TH STREET, NW SUITE 500 WASHINGTON, DC 20005				
EXAMINER				
MEHTA, HONG T				
ART UNIT		PAPER NUMBER		
1784				
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06/18/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/568,759

Applicant(s)

HARANO, YUTAKA

Examiner

HONG MEHTA

Art Unit

1784

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 9-15 is/are pending in the application.
- 4a) Of the above claim(s) 6-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 9-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SO/08)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Interval Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date February 21, 2006, December 7, 2007 and
November 6, 2009

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-5 and 9-15 in the reply filed on April 21, 2010 is acknowledged.

Claim Objections

Claims 1-5, and 9-15 are objected to because of the following informalities: the phrase "for testing for detecting" appears repetitive. Should one or the other of the two terms "testing" or "detecting" be deleted? Appropriate correction is required.

- 2.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 1, 2, 4, 5, 9, 11, 13 and 14 rejected under 35 U.S.C. 102(b) as being anticipated by Harano et al. ("Evaluation of Metabolic Effectiveness of Exercise Habit Using Respiratory Analyses and a Newly Developed Cookie Test").**
5. **Regarding claims 1 and 2**, Harano et al. discloses a cookie food product comprising 75 grams of flour starch (carbohydrates) and 24 grams of fat (p. A260, column 1, second paragraph) which corresponds to a weight ratio of 3.1:1 of flour starch (carbohydrates) to fat. Harano et al. does not specifically exact units as cited in claim 1, "100 parts by weight of carbohydrates and 20 to 40 parts by weight of fat", however the

cited range corresponds weight ratio of 2.5:1 to 5:1 (carbohydrates: fat) to which Harano's weight ratio of 3.1:1 of flour starch (carbohydrates) to fat is within range of the cited claim.

6. **Regarding claims 4, 5, 9, 11, 13 and 14**, Harano et al. discloses the cookie food product is use in evaluation of metabolic effectiveness including blood measurement for hyperinsulinemia, glucose intolerance and insulin resistance (p. A260, column 1, second paragraph). Additionally, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Harano et al. discloses cookie food product with amounts of carbohydrates and fat as claimed, therefore the Harano's cookie food product is expected to perform the same function or intended use as cited in the claims.

7. **Claims 1, 4, 5 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Palmason et al. (WO 97/02050).**

8. **Regarding claim 1**, Palmason et al. discloses a solid oral diagnostic test meal with carbohydrate source and fat (pg. 15) and weight of 50 grams carbohydrate to 11.3 grams of fat with corresponds to ratio of carbohydrates to fat of 4.4:1 (pg. 29, Example 3, Table 1). Palmason et al. does not specifically exact units as cited in claim 1, "100 parts by weight of carbohydrates and 20 to 40 parts by weight of fat", however the cited range corresponds weight ratio of 2.5:1 to 5:1 (carbohydrates: fat) to which Palmason's weight ratio of 4.4:1 is within range of the cited claim.

9. **Regarding claims 4, 5 and 13**, Palmason et al. discloses a solid oral diagnostic test meal used in evaluation of diabetes, glucose and insulin levels (Abstract).

Additionally, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Palmason et al. discloses a solid oral diagnostic test meal with amounts of carbohydrates and fat as claimed, therefore Palmason's food product is expected to perform the same function or intended use as cited in the claims.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 3, 10, 12, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harano et al. ("Evaluation of Metabolic Effectiveness of Exercise Habit Using Respiratory Analyses and a Newly Developed Cookie Test").

13. Harano et al. discloses the cookie food product is use in evaluation of metabolic effectiveness including blood measurement for hyperinsulinemia, glucose intolerance and insulin resistance (p. A260, column 1, second paragraph). Harano et al. is silent regarding the cookie providing 460 to 600 kilocalories. However, it would have been obvious to one of ordinary skill in the art to optimize amounts of ingredients such as carbohydrates and fat in the cookie formulation to obtain a desired caloric amount in the food for desired nutrition.

14. Claims 3, 10, 12, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmason et al. (WO 97/02050).

15. Palmason et al. discloses a solid oral diagnostic test meal in a form of cookie (pg. 20, lines 11-12) is use in evaluation including diabetes, glucose and insulin levels (Abstract). Palmason et al. is silent regarding the cookie providing 460 to 600 kilocalories. However, it would have been obvious to one of ordinary skill in the art to optimize amounts of ingredients such as carbohydrates and fat in the cookie formulation to obtain a desired caloric amount in the food for desired nutrition.

16. Claims 2, 9, 11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmason et al. (WO 97/02050) and in further view of Harano et al. ("Evaluation of Metabolic Effectiveness of Exercise Habit Using Respiratory Analyses and a Newly Developed Cookie Test").

17. Palmason et al. disclose the claimed invention as discussed above in claim 1. Palmason et al. discloses a solid oral diagnostic test meal in the form of a cookie (pg. 20, lines 11-12) for use in evaluation of diabetes, glucose and insulin levels (Abstract). Palmason et al. does not disclose a cookie with 73 to 77 grams of carbohydrates and 15 to 30 grams of fat.
18. However, Harano et al. discloses a cookie food product comprising 75 grams of flour starch (carbohydrates) and 24 grams of fat (p. A260, column 1, second paragraph). Harano et al. discloses the cookie is used in evaluation of metabolic effectiveness including blood measurement for hyperinsulinemia, glucose intolerance and insulin resistance (p. A260, column 1, second paragraph). It would have been obvious to one of ordinary skill in the art to use the amount of carbohydrates and fat taught by Harano in Palmason's cookie because the amount of carbohydrates and fat taught by Harano are known amounts for cookie formulation for evaluating metabolic effectiveness in glucose intolerance and insulin resistance.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG MEHTA whose telephone number is (571)270-7093. The examiner can normally be reached on Monday thru Thursday, from 7:30 am to 4:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer McNeil can be reached on 571-272-1540. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1784

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Htm

/Jennifer C. McNeil/

Supervisory Patent Examiner, Art Unit 1784